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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|-----------------------|------------------|
| 09/757,011 | 01/09/2001 | Vassil Iliya Ognyanov | 317743-103C | 7091 |
| 25561 | 7590 | 09/17/2004 | EXAMINER | |
| JOHN W. RYAN C/O DECHERT LLP PRINCETON PIKE CORPORATION CENTER P.O. BOX 5218 PRINCETON, NJ 08543-5218 | | | COLEMAN, BRENDA LIBBY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
| DATE MAILED: 09/17/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/757,011 | Applicant(s) OGNYANOV ET AL. | |
| | Examiner Brenda Coleman | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 43-76 are pending in the application.

This action is in response to applicants' amendment dated June 23, 2004.

Claims 43 and 62 have been amended and claims 75 and 76 are newly added.

Response to Arguments

Applicant's arguments filed June 23, 2004 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 1) maintained in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 4) in the last office action, which is hereby **withdrawn**.
3. The applicant's filing of a terminal disclaimer is sufficient to overcome the obviousness-type double patenting rejection labeled paragraph 5) in the last office action, which is hereby **withdrawn**.

In view of the amendment dated June 23, 2004, the following new grounds of rejection apply:

Election/Restrictions

4. Objection is made to claims 43-76 as containing non-elected subject matter. The claimed compounds, compositions, and methods that employ them present a variable

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core. The formula contains compounds drawn to the non-elected inventions. The applicants election of Group II of the restriction requirement presented in the parent application in the preliminary amendment filed January 9, 2001. Group II was as follows: Claims 1, 3-14 and 18-27, drawn to compounds, compositions and method of use where at least one of the substituents R^x and R^y is an oxygen or sulfur containing hetero ring and the other is non-nitrogen containing hetero ring with no additional heterocyclic rings as shown in species A32, A41, A42, A140 and A161. The compounds as claimed herein include nitrogen containing hetero rings in the definition of R^{xa} and R^{ya} (last line on page 2); in the definition of R^q , R^r and R^s where R^q , R^r and R^s contains a nitrogen atom (line 7 on page 3 and in line 9 of claim 62); the definition of R^5 where R^5 is tetrazol-5-yl (line 21 on page 4); the definition of R^{23} and R^{24} where R^{23} and R^{24} can be combined to include 1,3-dioxolane or 1,3-dioxane (see lines 1-2 on page 5); and the definition of R^{13} and R^{14} where R^{13} and R^{14} together with the attached nitrogen atom can form a 5 to 7-membered ring (see lines 13-14 on page 5).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 43-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 43-45, 48, 50-58, 60-65, 68-73, 75 and 76 are vague and indefinite in that it is not known what is meant by the definition of R^2 where R^2 **comprises**

in (b) which is open ended and reads on more than is positively recited. See line 8 in claim 43.

b) Claims 43-65 and 68-76 are vague and indefinite in that it is not known what is meant by the definition of heteroaryl where heteroaryl **comprises** in (a) which is open ended and reads on more than is positively recited. See line 1 on page 3.

c) Claims 43-65 and 68-76 are vague and indefinite in that it is not known what is meant by the definition of R^{xa} and R^{ya} where R^{xa} and R^{ya} **comprising** in (i.) which is open ended and reads on more than is positively recited. See line 20 on page 3.

d) Claims 43-65 and 68-76 are vague and indefinite in that it is not known what is meant by the definition of R^{xa} and R^{ya} where R^{xa} and R^{ya} **comprises** in (d) which is open ended and reads on more than is positively recited. See line 24 on page 3.

e) Claims 43-56, 59-65 and 68-76 are vague and indefinite in that it is not known what is meant by the definition of the second bridge between R^{xa} and R^{ya} where R^{xa} and R^{ya} is as set forth below, which it is not. See line 24 on page 3.

f) Claims 43-55, 59-72, 75 and 76 are vague and indefinite in that it is not known what is meant by the definition of R^1 where R^1 **comprises**, which is open ended and reads on more than is positively recited. See line 1 on page 4.

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- g) Claims 43-52, 55-65 and 68-76 are vague and indefinite in that it is not known what is meant by the oxygen of R^{15} and the sulfur of R^{16} where R^{15} does not contain an oxygen atom and R^{16} does not contain a sulfur atom.
- h) Claim 57 recites the limitation "completes a single bond linking two Ar rings of R^{xa} and R^{ya} or is (C1-C2) alkylene or -CH=CH-" in the definition of R^{21} . There is insufficient antecedent basis for this limitation in the claim.
- i) Claim 58 recites the limitation "-CH₂CH₂- or CH=CH" in the definition of R^{21} . There is insufficient antecedent basis for this limitation in the claim.
- j) Claims 64, 65 and 72 are vague and indefinite in that it is not known what is meant by the composition **comprising**, which is open ended and reads on more than is positively recited. See line 1 of claim 64.
- k) Claim 66 recites the limitation "OR¹⁵" in the definition of R^5 . There is insufficient antecedent basis for this limitation in the claim.
- l) Claims 68-71, 75 and 76 are vague and indefinite in that it is not known what is meant by the method of use where each disorder listed is **comprising**, which is open ended and reads on more than is positively recited. See lines 1, 3, 4, 5, 6, 7, 8 and 10 of claim 68; lines 2, 3 and 4 of claim 70; and line 1 of claim 71.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
September 16, 2004